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TO: Examiner Marianne Allen / Supervisor Michael Woodward

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USPTO REFERENCE: Applicant: Sibley et al.

Serial No.: 09/829,631

Filed: April 10, 2001

Title: THE ST-B17 SEROTONIN RECEPTOR

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MESSAGE: *Attached for filing in the above-referenced application are:*

INFORMAL COMMUNICATION FOR DISCUSSION PURPOSES ONLY in 4 pages; and marked up copy of MPEP 201.06(c) in 4 pages.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Sibley et al.
Appl. No.	:	09/829,631
Filed	:	April 10, 2001
For	:	THE ST-B17 SEROTONIN RECEPTOR.
Examiner	:	Allen, Marianne P.
Group Art Unit	:	1631

INFORMAL COMMUNICATION FOR DISCUSSION PURPOSES ONLY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In preparation for the in-person interview scheduled for Tuesday, 17 March 2004, at 10 a.m., please consider the following proposed amendment (for which support is found throughout the specification, for example, at 22:37):

Appl. No. : 09/829,631
Filed : April 10, 2001

PROPOSED AMENDMENTS TO THE CLAIMS

Please amend Claim 17 as follows under this proposed amendment:

1-16 PREVIOUSLY CANCELED

17. (Currently amended) An isolated nucleotide sequence encoding a serotonin receptor protein St-B17, said nucleotide sequence being selected from:

(a) a nucleotide sequence comprising SEQ ID NO:7;

(b) a nucleotide sequence comprising SEQ ID NO:12;

(c) a human nucleotide sequence hybridizing under moderate stringency conditions at 6XSSC and 55°C, pH7, to a 1192 bp XmaI-BstXI or a 655 bp BamHI-EagI fragment from SEQ ID NO:7; or

(d) a nucleotide sequence encoding a protein having the amino acid sequence shown by SEQ ID NO:8 or SEQ ID NO:13.

18. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (a).

19. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (b).

20. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (c).

21. (Previously presented) The nucleotide sequence according to Claim 17, wherein said nucleotide sequence is selected from (d).

22. (Previously presented) A recombinant construct comprising the nucleotide sequence according to Claim 17, operably linked to a heterologous promoter.

23. (Previously presented) The recombinant construct according to Claim 22, which is an expression vector.

24. (Previously presented) The recombinant construct according to Claim 23, which is a eukaryotic expression vector.

25. (Previously presented) A mammalian cell line comprising the nucleotide sequence of Claim 17, said mammalian cell line expressing St-B17 serotonin receptor.

26. (Previously presented) The cell line of Claim 25, wherein said cells are derived from a human.

27. (Previously presented) The cell line of Claim 26, wherein said cells are HEK 293.

Appl. No. : 09/829,631
Filed : April 10, 2001

28. (Previously presented) An isolated protein encoded by the nucleotide sequence of any of Claims 17-21.

Appl. No. : 09/829,631
Filed : April 10, 2001

By containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter and cannot be redesignated as a continuation-in-part

Additionally, please consider the attached marked-up copy of MPEP 201.06(c) indicating that the Patent Office strongly recommends that a continuation application *contain* only the desired set of claims rather than *add* the desired set of claims by preliminary amendment. The filing of the desired set of claims (Claims 1-16) rather than adding the desired set of claims by preliminary amendment resulted in the office action determining that the continuation application contains new matter and must be redesignated as a continuation-in-part. Nevertheless, the MPEP additionally indicates that the prior set of claims was properly incorporated by reference by a statement in the application transmittal letter specifically enumerating the prior application. There is no dispute that, other than the desired set of claims, the specification is identical to the prior specification (except for the introduction of SEQ ID identifiers). Assuming for the sake of argument that Claims 1-16 did not meet the requirement under 35 USC 112/1 for written description (although they were *not* rejected under 35 USC 112/1 for lack of written description), the claims have been canceled and replaced with Claims 17-28. By containing the desired set of claims rather than adding the desired set of claims by preliminary amendment, the continuation application does not contain new matter (although there is a dispute as to whether subsequently-canceled Claims 1-16 meet the requirement under 35 USC 112/1 for written description), the specification of which is otherwise identical to the prior specification (except for the introduction of SEQ ID identifiers), properly incorporates by reference the prior set of claims, conforms with the procedure strongly recommended by the Patent Office, and cannot be redesignated as a continuation-in-part.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3/5/04

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201.06(e)

MANUAL OF PATENT EXAMINING PROCEDURE

201.06(c) 37 CFR 1.53(b) and 37 CFR 1.63(d) Divisional-Continuation Procedure [R-1]**37 CFR 1.53. Application number, filing date, and completion of application.**

(b) *Application filing requirements - Nonprovisional application.* The filing date of an application for patent filed under this section, except for a provisional application under paragraph (c) of this section or a continued prosecution application under paragraph (d) of this section, is the date on which a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75, and any drawing required by § 1.81(a) are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date. A continuing application, which may be a continuation, divisional, or continuation-in-part application, may be filed under the conditions specified in 35 U.S.C. 120, 121 or 365(c) and § 1.78(a).

(1) A continuation or divisional application that names as inventors the same or fewer than all of the inventors named in the prior application may be filed under this paragraph or paragraph (d) of this section.

(2) A continuation-in-part application (which may disclose and claim subject matter not disclosed in the prior application) or a continuation or divisional application naming an inventor not named in the prior application must be filed under this paragraph.

37 CFR 1.63. Oath or Declaration.

(d)(1) A newly executed oath or declaration is not required under § 1.51(b)(2) and § 1.53(f) in a continuation or divisional application, provided that:

(i) The prior nonprovisional application contained an oath or declaration as prescribed by paragraphs (a) through (c) of this section;

(ii) The continuation or divisional application was filed by all or by fewer than all of the inventors named in the prior application;

(iii) The specification and drawings filed in the continuation or divisional application contain no matter that would have been new matter in the prior application; and

(iv) A copy of the executed oath or declaration filed in the prior application, showing the signature or an indication thereon that it was signed, is submitted for the continuation or divisional application.

(2) The copy of the executed oath or declaration submitted under this paragraph for a continuation or divisional application must be accompanied by a statement requesting the deletion of the name or names of the person or persons who are not inventors in the continuation or divisional application.

(3) Where the executed oath or declaration of which a copy is submitted for a continuation or divisional application was originally filed in a prior application accorded status under § 1.47, the copy of the executed oath or declaration for such prior application must be accompanied by:

(i) A copy of the decision granting a petition to accord § 1.47 status to the prior application, unless all inventors or legal representatives have filed an oath or declaration to join in an application accorded status under § 1.47 of which the continuation or divisional application claims a benefit under 35 U.S.C. 120, 121, or 365(c); and

(ii) If one or more inventor(s) or legal representative(s) who refused to join in the prior application or could not be found or reached has subsequently joined in the prior application or another application of which the continuation or divisional application claims a benefit under 35 U.S.C. 120, 121, or 365(c), a copy of the subsequently executed oath(s) or declaration(s) filed by the inventor or legal representative to join in the application.

(4) Where the power of attorney (or authorization of agent) or correspondence address was changed during the prosecution of the prior application, the change in power of attorney (or authorization of agent) or correspondence address must be identified in the continuation or divisional application. Otherwise, the Office may not recognize in the continuation or divisional application the change of power of attorney (or authorization of agent) or correspondence address during the prosecution of the prior application.

(5) A newly executed oath or declaration must be filed in a continuation or divisional application naming an inventor not named in the prior application.

IN GENERAL

37 CFR 1.53(b) is the section under which all applications are filed EXCEPT: (A) an application resulting from entry of an international application into the national stage under 35 U.S.C. 371 and ** 37 CFR 1.495; (B) a provisional application under 35 U.S.C. 111(b) and 37 CFR 1.53(c); or (C) a continued prosecution application (CPA) under 37 CFR 1.53(d). Applications submitted under 37 CFR 1.53(b), as well as CPAs submitted under 37 CFR 1.53(d), are applications, filed under 35 U.S.C. 111(a). An application filed under 37 CFR 1.53(b) may be an original, a continuation, a divisional, a continuation-in-part, or a substitute. (See MPEP § 201.09 for substitute application.) The application may be for a "utility" patent under 35 U.S.C. 101, a design patent under 35 U.S.C. 171, a plant patent under 35 U.S.C. 161, or a reissue under 35 U.S.C. 251.

37 CFR 1.53(b) is the "default" application. An application that is not (A) the result of the entry of an international application into the national stage after

TYPES, CROSS-NOTING, AND STATUS OF APPLICATION

201:06(c)

compliance with 35 U.S.C. 371 and ** 37 CFR 1.495, (B) a provisional application under 37 CFR 1.53(c), or (C) a CPA under 37 CFR 1.53(d), is an application filed under 37 CFR 1.53(b). An application will be treated as one filed under 37 CFR 1.53(b) unless otherwise designated.

In order to be complete for filing date purposes, all applications filed under 37 CFR 1.53(b) must include a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to 37 CFR 1.71 and at least one claim pursuant to 37 CFR 1.75, and any drawing required by 37 CFR 1.81(a). The statutory filing fee and an oath or declaration in compliance with 37 CFR 1.63 (and 37 CFR 1.175 (if a reissue) or 37 CFR 1.162 (if for a plant patent)) are also required by 37 CFR 1.51(b) for a complete application, but the filing fee and oath or declaration may be filed after the application filing date upon payment of the surcharge set forth in 37 CFR 1.16(e). See 37 CFR 1.53(f).

Any application filed on or after December 1, 1997, which is identified by the applicant as an application filed under 37 CFR 1.60 will be processed as an application under 37 CFR 1.53(b) (using the copy of the specification, drawings and signed oath/declaration filed in the prior application supplied by the applicant). Any submission of an application including or relying on a copy of an oath or declaration that would have been proper under 37 CFR 1.60 will be a proper filing under 37 CFR 1.53(b).

A new application containing a copy of an oath or declaration under 37 CFR 1.63 referring to an attached specification is indistinguishable from a continuation or divisional application containing a copy of an oath or declaration from a prior application submitted pursuant to 37 CFR 1.63(d). Unless an application is submitted with a statement that the application is a continuation or divisional application, see 37 CFR 1.78(a)(2), the Office will process the application as a new non-continuing application. Applicants are advised to clearly designate any continuation, divisional, or continuation-in-part application as such to avoid the issuance of a filing receipt that does not indicate that the application is a continuation, divisional, or continuation-in-part.

OATH/DECLARATION

37 CFR 1.63(d) provides that a newly executed oath or declaration is not required in a continuation or divisional application filed by all or by fewer than all of the inventors named in a prior nonprovisional application containing a signed oath or declaration as required by 37 CFR 1.63, provided that a copy of the signed oath or declaration filed in the prior application is submitted for the continuation or divisional application and the specification and drawings filed in the continuation or divisional application do not contain any subject matter that would have been new matter in the prior application. The copy of the oath or declaration must show the signature of the inventor(s) or contain an indication thereon that the oath or declaration was signed (e.g., the notation "/s/" on the line provided for the signature).

It is not necessary to have the inventor sign a new oath or declaration merely to include a reference to the duty of disclosure if the parent application was filed prior to January 1, 1978, to indicate that the inventor has reviewed and understands the contents of the application if the parent application was filed prior to October 1, 1983, or to indicate the inventor's post office address if the parent application was filed prior to December 1, 1997, and the inventor's mailing or post office address is identified elsewhere in the application.

When a copy of an oath or declaration from a prior application is filed in a continuation or divisional application under 37 CFR 1.53(b), special care should be taken by the applicant to ensure that the copy is matched with the correct application file. Applicant should file the copy of the oath or declaration with a cover letter explaining that the copy of the oath or declaration is for the attached application or for a previously-filed 37 CFR 1.53(b) application (identified by application number which consists of a two-digit series code, e.g., 08/ and a six-digit serial number, e.g., 123,456). An adhesive label may be attached to the front of the copy of the oath or declaration. The label should clearly state that the copy of the oath or declaration is intended for the attached application submitted therewith or for Application No. XX/YYY,YYY. During initial processing, attachments (e.g., a cover letter) to application papers may be separated. Therefore, applicant should not rely solely upon a cover letter. Note: 37 CFR 1.5(a) states that no

201.06(c)

MANUAL OF PATENT EXAMINING PROCEDURE

correspondence relating to an application should be filed prior to receipt of the application number information from the Patent and Trademark Office.

37 CFR 1.63(d) requires a copy of the signed oath or declaration from the prior application. In instances in which the oath or declaration filed in the prior application is itself a copy of an oath or declaration from a prior application, either a copy of the copy of the oath or declaration in the prior application or a direct copy of the original oath or declaration is acceptable, as both are a copy of the oath or declaration in the prior application, see 37 CFR 1.4(d)(1)(ii).

The patent statute and rules of practice do not require that an oath or declaration include a date of execution, and no objection should be made to an oath or declaration because it lacks either a recent date of execution or any date of execution. The applicant's duty of candor and good faith including compliance with the duty of disclosure requirements of 37 CFR 1.56 is continuous and applies to the continuing application.

A newly executed oath or declaration is required in a continuation or divisional application filed under 37 CFR 1.53(b) naming an inventor not named in the prior application, and in a continuation-in-part application.

SPECIFICATION AND DRAWINGS

A continuation or divisional application may be filed under 35 U.S.C. 111(a) using the procedures set forth in 37 CFR 1.53(b), by providing: (A) a copy of the prior application, including a copy of the signed oath or declaration in such prior application, as filed; (B) a new specification and drawings and a copy of the signed oath or declaration as filed in the prior application provided the new specification and drawings do not contain any subject matter that would have been new matter in the prior application; or (C) a new specification and drawings and a newly executed oath or declaration provided the new specification and drawings do not contain any subject matter that would have been new matter in the prior application. If a continuation or divisional application filed with a newly executed oath or declaration contains subject matter that would have been new matter in the prior application, the application will have to be amended to indicate that it is a continuation-in-part application rather than a continuation or a divisional application.

The specification and drawings of a continuation or divisional application filed under 37 CFR 1.53(b) are not limited to a reproduction or "true copy" of the prior application, i.e., the applicant may revise the specification for clarity or contextual purposes vis-à-vis the specification originally filed in the prior application in the manner that an applicant may file a substitute specification, see 37 CFR 1.125, or amend the drawings of an application so long as it does not result in the introduction of new matter. It is the applicant's responsibility to review any new specification or drawings submitted for a continuation or divisional application under 37 CFR 1.53(b) and 37 CFR 1.63(d) to determine that it contains no new matter. An applicant is advised to simply file a continuing application with a newly executed oath or declaration when it is questionable as to whether the continuing application adds material that would have been new matter if presented in the prior application. If one or more claims are allowed in the continuation or divisional application which are directed to matter shown and described in the prior nonprovisional application but not claimed in the prior application, the applicant should be required to file a supplemental oath or declaration under 37 CFR 1.67(b).

Where a copy of the oath or declaration from a prior application was filed in a continuation or divisional application, if the examiner determines that new matter is present relative to the prior application, the examiner should so notify the applicant in the next Office action (preferably the first Office action). The examiner should require: (A) a new oath or declaration along with the surcharge set forth in 37 CFR 1.16(e); and (B) that the application be redesignated as a continuation-in-part.

>Any utility or plant patent application, including any continuing application, that will be published pursuant to 35 U.S.C. 122(b) should be filed under 37 CFR 1.53(b) with a specification (including the claims), and drawings, that the applicant would like to have published. This is important because the Office will generally publish the specification (including the claims) and drawings as filed and, under 35 U.S.C. 154(d), a patentee may obtain provisional rights if the invention claimed in a patent is substantially identical to the invention claimed in the application publication. Filing a continuing application under 37 CFR 1.53(b) with a preliminary amendment (which makes

TYPES, CROSS-NOTING, AND STATUS OF APPLICATION

201.06(c)

all the desired changes to the specification, including adding, deleting or amending claims) is NOT recommended because the changes made by the preliminary amendment will generally not be reflected in the patent application publication even if the preliminary amendment is referred to in an oath or declaration. As noted above, a continuation or divisional application filed under 37 CFR 1.53(b) may be filed with a new specification and corrected drawings, along with a copy of an oath or declaration from a prior (parent) application, provided the new specification and drawings do not contain any subject matter that would have been new matter in the prior application. Thus, the new specification and corrected drawings may include some or all of the amendments entered during the prosecution of the prior application(s), as well as additional amendments submitted for clarity or contextual purposes, and a new set of claims. In order to have a patent application publication of a continuation or divisional application contain only a desired set of claims, rather than the set of claims in the prior application, it is strongly recommended that the continuation or divisional application be filed under 37 CFR 1.53(b) with a new specification containing only the desired set of claims. If the continuation or divisional application is filed with a copy of the specification from the prior application along with a preliminary amendment which cancels, amends and/or adds new claims, publication of the application, as amended, would only occur if a copy of the specification (with the amended set of claims) was also submitted through the Office's Electronic Filing System (EFS).<



INCORPORATION BY REFERENCE

In a continuation or divisional application, the safeguard (petition and fee under former 37 CFR 1.60(b)) concerning the filing of an application lacking all of the pages of the specification or sheets of drawings of the prior application has not been retained in 37 CFR 1.53(b) since the specification and drawings of a continuation or divisional application are not limited to a reproduction or a "true copy" of the prior application. As a safeguard, however, an applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby

incorporated herein by reference." The statement may appear in the specification or in the application transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference.

A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed.

For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. >An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application. See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980).<

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p).